



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 19, 2020

Kathryn Rosario
Regulatory Assurance Specialist
Lonza, LLC
412 Mt. Kemble Ave. Suite 200S
Morristown, NJ 07960

Subject: PRIA Label Amendment – Emerging Viral Pathogens Claim
Product Name: Carbosan 20D
EPA Registration Number: 6836-357
Application Date: May 7, 2020
Decision Number: 562757

Dear Ms. Rosario:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OIE, the pathogen's viral subgroup is large non-enveloped and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Norovirus [ATCC VR-782] is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Michael McCarroll by phone at 703-347-0147, or via email at mccarroll.michael@epa.gov.

Sincerely,



Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Note to Reviewer:

[Items in brackets [AAA] are optional and may/may not be included on final label]

{Items in braces {AAA} are for information purposes and will not appear on final label}

CARBOSAN 20D

A C C E P T E D

08/19/2020

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 6836-357

Disinfectant - Sanitizer - Deodorizer – Virucide*

Effective as a disinfectant in the presence of 5% serum contamination

For Home, Commercial, Institutional and Industrial Use

For Food, Dairy, Beverage, Meat, Poultry, Egg and Seafood Processing and Farm Use

For Farm, School, Dairy, Restaurant, Food Handling and Processing Areas, Bar and Institutional Kitchen Use

For use in federally inspected meat and poultry plants

An effective sanitizer for use on food contact surfaces

Active Ingredients:

Didecyl dimethyl ammonium carbonate and Didecyl dimethyl ammonium bicarbonate20.0%

Other Ingredients.....80.0%

Total.....100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

See [left] [side] [right] [back] panel for Precautionary Statements

EPA Reg. No. 6836-357

EPA Est. No. (insert EPA Est. No. here)

Net Contents: (as indicated on container)

[DOT symbols]

[Country of origin (insert country)]

[Manufactured in (insert country)]

[BARCODE]

Manufactured by:

LONZA, LLC

412 Mt. Kemble Ave. Suite 200S

Morristown, NJ 07960

Precautionary Statements

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed or inhaled. Do not get in eyes, on skin or on clothing. Do not breathe vapor. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Harmful if absorbed through skin. Wear protective eyewear (goggles or face shield), protective clothing and protective (rubber or chemical resistant) gloves.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

{If container size is 5 gallons or greater, use the following Environmental Hazards statement:}

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

{Note to reviewer: The following is considered optional marketing language.}

- Concentrate [Concentrated]
- Deodorizes [Deodorizer]
- [**Carbosan 20D**] Contains no [phosphates] phosphorous [or phosphorous compounds].
- This product may be applied through low-pressure sprayers,
- Use this product to clean, sanitize and disinfect non-porous ambulance equipment and surfaces. Rinse with clean water all equipment that will come in prolonged contact with skin before reuse.
- This product may be used to deodorize coolers, buckets, garbage pails and other areas where strong odors may develop.
- Cleans [and disinfects] every day kitchen messes.
- Use [on] [to clean and disinfect] nonporous athletic mats, wrestling mats, gymnastic mats, exercise equipment and training tables.

Carbosan 20D

- delivers non-acid performance in an economical concentrate.
- is an economical concentrate
- can be diluted for use with a mop and bucket, trigger sprayers, sponge or by soaking.
- improves labor results by effectively controlling odors.
- for use with trigger sprayers.
- deodorizes by killing microorganisms that cause offensive odors.
- cleans, disinfects and deodorizes in one labor saving step.
- is formulated for use in daily maintenance programs.
- will not leave grit or soap scum.
- is a complete, chemically balanced sanitizer that provides clear use solutions even in the presence of hard water.
- is a proven "one-step" disinfectant which is effective in water up to 200 ppm hardness in the presence of 5% serum contamination.¹
- has been cleared by the EPA in 40 CFR §180.940(a) for use on food processing equipment, utensils and other food-contact articles [at a concentration of 150 – 400 ppm active].
- is a sanitizer for use in all federally inspected meat and poultry plants, institutional and industrial facilities.
- can be used on food contact surfaces [in a concentration range of 150 – 400 ppm active].
is an effective sanitizer.
- **Carbosan 20D** is an effective sanitizer.
- [Kills] [Eliminates 99.9%] [Removes] [Destroys] (*Insert pathogen or pathogens from lists on page 7*) on [pre-cleaned] environmental surfaces

Cross-contamination is of major [housekeeping] [food safety] concern. **Carbosan 20D** has been formulated to aid in the reduction of cross-contamination between treated surfaces in schools, institutions, and industry.

Regular, effective cleaning and sanitizing of equipment, utensils, and work or dining surfaces which could harbor food poisoning microorganisms minimizes the probability of contaminating food during preparation, storage or service. Effective cleaning will remove soil and prevent the accumulation of food residues, which may decompose or support the rapid development of food poisoning organisms or toxins. Application of effective sanitizing procedures reduces the number of those disease organisms which may be present on equipment and utensils after cleaning, and reduces the potential for the transfer, either directly through tableware such as glasses, cups and flatware or indirectly through food.

To prevent cross-contamination between treated surfaces kitchenware and food-contact surfaces of equipment must be washed, rinsed with potable water and sanitized after each use and following any interruption of operation during which time contamination may have occurred.

{Note to reviewer: The following is considered optional marketing language.}

Where equipment and utensils are used for the preparation of foods on a continuous or production-line basis, utensils and the food-contact surfaces of equipment must be washed, rinsed with potable water and sanitized at intervals throughout the day on a schedule based on food temperature, type of food, and amount of food particle accumulation.

Articles that can be immersed in solution must remain in solution for 60 seconds.

Articles or surfaces too large for immersing must be thoroughly wetted or flooded by rinsing, spraying or swabbing.

Allow all sanitized surfaces to drain [and air dry].

Carbosan 20D fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinances Recommendations of the U.S. Public Health Services in waters up to 500 ppm of hardness calculated as CaCO₃ when evaluated by the AOAC Germicidal and Detergent Sanitizer Method.

Use **Carbosan 20D**:

- to disinfect salon / barber tools and instruments: combs, brushes, scissors, blades and manicure instruments.
- in kitchens and other household areas.
- as a sanitizer for all surfaces not always requiring a rinse in official establishments operating under the Federal meat, poultry, shell egg grading and egg products inspection programs.
- as a sanitizer on dishes, glassware, and utensils.
- as a sanitizer in bottling and beverage dispensing equipment.
- as a sanitizer in sanitary filling of bottles and cans.
- in sanitizing bottles or cans in the final rinse application, and for external spraying of filler and closing machines.
- as a sanitizer in beer fermentation and holding tanks.
- as a Food-Grade Shell-Egg sanitizer, with best results achieved in water temperatures ranging from 78°F. – 110°F. Carbosan 20D may be applied through automatic washing systems, immersion tanks, foaming apparatus, and low pressure sprayers.
- in federally inspected meat and poultry facilities [as a sanitizer for all surfaces not always requiring a rinse].

{Note to reviewer: The following is considered optional marketing language.}

[AREAS OF USE:]

Use **Carbosan 20D** in:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding area of use. The graphics will only represent individual objects or outsides or insides of buildings as described below. No people, animal or food will be depicted in graphics.}

Homes [households]	Fisheries
Kitchens	Fish processing plants
Day care centers	Food establishments
Nurseries	Food processing plants
	Food preparation areas
	Food storage areas
Airplanes	Hotels
Airports	Ice cream processing plants
Bagel Stores	Institutional facilities
Bars	Institutional kitchens
Bathrooms	Institutions
Beer fermentation and holding tanks	Liquor stores
Beverage Plants	Meat processing plants
Boats	Meat producing facilities
Bottling or pre-mix dispensing equipment	Milk processing plants
Bottle Washing	Milk storage and handling systems
Buses	Milk tanks [bulk]
Cafeterias	Milk pail inflations and tubing
Campers	Mobile homes
Camp grounds	Motels
Cheese factories	Pizza parlors
Citrus processing plants	Poultry processing plants
Coffee shops	Poultry producing facilities
Colleges	Prisons
Convenience stores	Processing plants [Milk, Citrus, Ice Cream]
Correctional facilities	Public facilities
Dairies	Restaurants
Dairy Farms	Schools
Dairy product dispensing equipment	Ships
Donut shops	Trains
Drinking fountains	Universities
Egg processing plants	USDA inspected food processing facilities
Factories	Wineries
Fast food operations	

Other suggested Uses: Homes, Veterinary Clinics, Fish Markets, Kennels, Trash Compactors, Offices, Beauty Salons, Locker Rooms, Health Spas, Conference rooms, Elevators, Smoking Areas, Lounges, Day Care Centers, Dry Cleaners, Theaters, Farms, Auditoriums and Churches.

{Note to reviewer: The following is considered optional marketing language.}

[TYPES OF SURFACES:]

Use **Carbosan 20D** on washable hard, nonporous surfaces of:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding type of surface. No people, animal or food will be depicted in graphics. Only exteriors of microwaves and refrigerators will be depicted. Toy graphics will be submitted to Agency for review.}

Appliances, exteriors	Refrigerated storage and display equipment ²
Beer fermentation and holding tanks	Silverware
Blenders	Sinks
Bottling or premix dispensing equipment	Stoves ² [stovetops ²]
Citrus processing equipment and holding tanks	Tables [picnic tables]
Coffee Pots	Tableware
Coffee Urns	Tea dispensers
Cooking utensils	Utensils
Coolers	Water dispensers [hot]
Counters [countertops]	
Countertop laminates	Chrome
Chopping blocks, plastic and other nonporous	Enamel
Cutlery	Fiberglass sinks
Cutting Boards, plastic and other nonporous	Glass
Dishes	Glazed ceramic
Drinking fountains	Glazed enameled surfaces
Eating Utensils	Glazed porcelain
Exhaust fans	Laminated surfaces
Food processors	Metal
Frozen Beverage Machines ²	Plastic [such as polystyrene or polypropylene]
Glassware [glasses]	Sealed granite
Highchairs	Sealed limestone
Ice Chests ²	Sealed marble
Ice Machines ²	Sealed Slate
Kitchen equipment	Sealed Stone
Microwave ovens	Sealed Terra cotta
Plastic Food Storage Containers	Sealed Terrazzo
Refrigerators ²	Stainless steel
Refrigerator bins ² used for meat, fruit, vegetables and eggs	Upholstery, vinyl and plastic
	Woodwork, finished

{Note to reviewer: The following is considered optional marketing language.}

Carbosan 20D is an effective sanitizer for use on food contact surfaces in 60 seconds at 150ppm-400 active and 500 ppm hard water against:

Campylobacter jejuni [ATCC 33560]
Escherichia coli [ATCC 11229]
Escherichia coli O157:H7 [ATCC 33150]
Klebsiella pneumoniae [ATCC 4352]
Listeria monocytogenes [ATCC 19115]
Salmonella typhimurim [ATCC 23564]
Staphylococcus aureus [ATCC 6538]
Yersinia enterocolitica [ATCC 23715]

Carbosan 20D is a [one-step] disinfectant, Bactericidal tested according to the current AOAC Germicidal Spray Test Method in the presence of 200 ppm hard water plus 5% organic serum.¹

Carbosan 20D is effective against:

[Bacteria:]
Salmonella enterica [Salmonella]
Escherichia coli O157:H7 [Pathogenic E. coli] [E. coli O157:H7]
Staphylococcus aureus

[Virus:]
*Norovirus [*Feline Calicivirus] [ATCC VR-782]

{Note to Reviewer: This product qualifies for the following emerging pathogen claims against large non-enveloped or enveloped viruses. The claims shall not appear on marketed (final print) product labels.}

EMERGING VIRAL PATHOGEN STATEMENT

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below."

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- Enveloped Viruses
- Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...follow the direction for use for the following organisms on the label:
Enveloped Viruses	Norovirus [ATCC VR-782]
Large Non-Enveloped Viruses	Norovirus [ATCC VR-782]

[Carbosan 20D] [Brand Name] [This Product] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, **[Carbosan 20D] [Brand Name] [This Product]** can be used against [name of emerging virus] when used in accordance with the directions for use against [Norovirus (ATCC VR-782)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

OR

[Name of illness/outbreak] is caused by [name of emerging virus]. **[Carbosan 20D] [Brand Name] [This Product]** kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [Norovirus (ATCC VR-782)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

Dilution:

Disinfection [1:341]	1 fl. oz. per 2 2/3 gallon of water
Sanitizer [1:512]	1.0 fl. oz. per 4 gallons of water
.....	[400 ppm active quat]
Sanitizer [1:1024]	0.5 fl. oz. per 4 gallons of water
.....	[200 ppm active quat]
Sanitizer [1:1365]	0.5 fl. oz. per 5 1/3 gallons of water
.....	[150 ppm active quat]
Virucide [1:556]	1.0 fl. oz. per 4.25 gallons of water
.....	[360 ppm active quat]

{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. [If you do not understand the label, find someone to explain it to you in detail.]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DISINFECTION DIRECTIONS:

Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

Preparation of Disinfectant Use-Solution:

[Add] [mix] 1 fl. oz. of **Carbosan 20D** per 2 2/3 gallons of water [1:342] or 3 fl. oz. per 8 gallons of water.

Apply use-solution to hard, nonporous surfaces, thoroughly wetting surfaces with a coarse trigger sprayer.

Treated surfaces must remain wet for 5 minutes. Wipe dry with a cloth, sponge or mop or allow to air dry. For visibly soiled areas pre-clean first.

Spray 6 - 8 inches from the surface; rub with a brush, sponge or cloth. Do not breathe spray. Note: Cover or remove all food products.

Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes as a disinfectant.

Prepare a fresh solution daily or more often if the solution becomes visibly dirty or diluted.

Preparation of Use-Solution for viral efficacy:

[Add] [mix] 1 fl. oz. of **Carbosan 20D** per 4.25 gallons of water [1:556]. Apply use-solution with a coarse trigger sprayer to hard, nonporous surfaces by spraying 6 - 8 inches from the surface, thoroughly wetting surfaces.

Allow surfaces to remain wet for 5 minutes. Wipe dry with a cloth, sponge or mop or allow to air dry. For visibly soiled areas pre-clean first.

For Food Contact Surfaces, Food Processing Equipment and Utensils in Dairies and Public Eating Establishments and Food Contact Surfaces, Food Processing Equipment and Utensils in Food Processing Plants [40 CFR 180.940 (a)]:

{Note to reviewer. On a final printed label, only one of the following dilution rates will be used in the sanitization sections below:}

1 fl. oz. of **Carbosan 20D** per 10 $\frac{2}{3}$ gallons of water [0.10 fl. oz. of **Carbosan 20D** per gallon of water] [150 ppm active quat]

{or}

1 fl. oz. of **Carbosan 20D** per 8 gallons of water [0.13 fl. oz. of **Carbosan 20D** per gallon of water] [200 ppm active quat]

{or}

1 fl. oz. of **Carbosan 20D** per 4 gallons of water [0.26 fl. oz. of **Carbosan 20D** per gallon of water] [400 ppm active quat]

{or}

1 fl. oz. of **Carbosan 20D** per 8 – 10 $\frac{2}{3}$ gallons of water [0.10 – 0.13 fl. oz. of **Carbosan 20D** per gallon of water] [150 – 200 ppm active quat]

{or}

1 fl. oz. of **Carbosan 20D** per 4 - 8 gallons of water [0.13 – 0.26 fl. oz. of **Carbosan 20D** per gallon of water] [200 – 400 ppm active quat]

{or}

1 fl. oz. of **Carbosan 20D** per 4 – 10 $\frac{2}{3}$ gallons of water [0.10 – 0.26 fl. oz. of **Carbosan 20D** per gallon of water] [150 – 400 ppm active quat]

TO SANITIZE FOOD CONTACT SURFACES:

{or}

TO SANITIZE FOOD CONTACT SURFACES, FOOD PROCESSING EQUIPMENT AND OTHER HARD SURFACES IN FOOD PROCESSING LOCATIONS, DAIRIES, RESTAURANTS AND BARS [IN A THREE COMPARTMENT SINK]:

For sanitizing hard non-porous surfaces of food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard nonporous surfaces.

Prior to application, remove visible food particles and soil by a pre-flush, or pre-scrape and, when necessary, pre-soak. Then thoroughly wash or flush objects with a good detergent or compatible cleaner, followed by a potable water rinse before application of the sanitizing solution.

Apply a use-solution of (insert appropriate dilution from box here) [or equivalent dilution] to the pre-cleaned hard surface, with a cloth, mop, sponge, [coarse] sprayer or by immersion, thoroughly wetting surfaces. Surfaces must remain wet for at least [one minute] [60 seconds] followed by adequate draining [and air drying]. Do not rinse.

Prepare fresh solution daily or more often if the use solution becomes diluted or soiled. For mechanical applications, use-solution may not be reused for sanitizing applications but may be reused for other purposes such as cleaning.

Apply to sink tops, counter tops, refrigerated storage and display equipment and other stationary surfaces by cloth, sponge [or] brush [or coarse spray].

Immerse pre-cleaned glassware, dishes, silverware, cooking utensils and other similar size food processing equipment in a solution of (insert appropriate dilution here) [or equivalent dilution] for at least 60 seconds. Drain thoroughly [and allow to air dry] before reuse. Do not rinse.

TO SANITIZE FOOD PROCESSING EQUIPMENT, UTENSILS, AND OTHER FOOD CONTACT ARTICLES REGULATED BY 40 CFR § 180.940(a) [IN A THREE COMPARTMENT SINK]:

1. Scrape, flush, or presoak articles [whether mobile or stationary] to remove visible food particles and soil.
2. Thoroughly wash articles with an appropriate detergent or cleaner.
3. Rinse articles thoroughly with potable water.
4. Sanitize by immersing articles with a use-solution of (*insert appropriate dilution here*) for at least 60 seconds. Articles too large for immersing must be thoroughly wetted by rinsing, spraying, or swabbing.
5. Remove immersed items from solution to drain.
6. Allow all items to air dry. Do not rinse.

Carbosan 20D can be used in accordance with the U.S. Public Health Service food service sanitization recommendations.

U.S. PUBLIC HEALTH SERVICE FOOD SERVICE SANITIZATION RECOMMENDATIONS CLEANING AND SANITIZING:

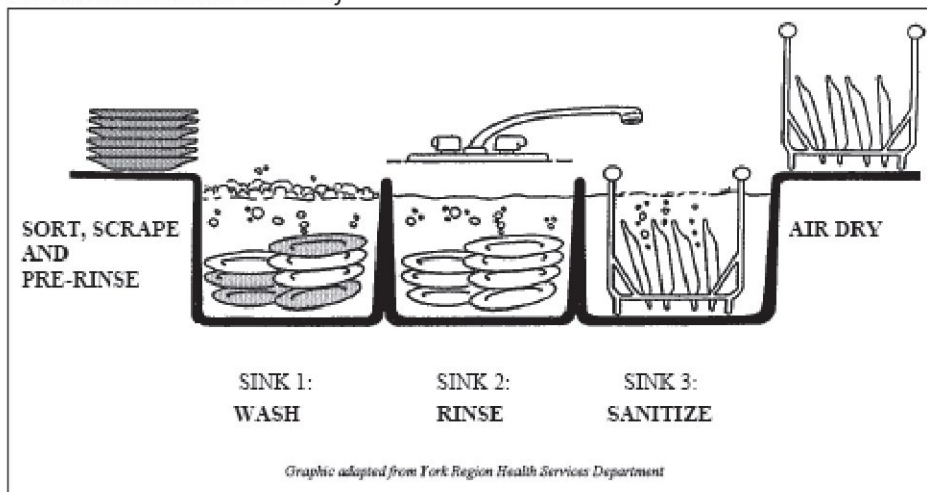
1. Equipment and utensils must be thoroughly pre-flushed or pre-scraped and when necessary, pre-soaked to remove visible food particles and soil.
2. Thoroughly wash equipment and utensils in hot detergent solution.
3. Rinse utensils and equipment thoroughly with potable water.
4. Sanitize equipment and utensils by immersion in a use solution of (*insert appropriate dilution here*) [or equivalent dilution] for at least 60 seconds [one minute] at a temperature of 75°F.
5. For equipment and utensils too large to sanitize by immersion, apply a use-solution of (*insert appropriate dilution here*) [or equivalent dilution] by rinsing, spraying or swabbing until thoroughly wet.
6. Allow sanitized surface to drain [and air dry]. Do not rinse.

WISCONSIN STATE BOARD OF HEALTH DIRECTIONS FOR EATING ESTABLISHMENTS

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner.
3. Rinse with clean water.
4. Sanitize in a solution of (*insert appropriate dilution here*). Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain board [to air-dry].
6. Prepare a fresh sanitizing solution at least daily or when visibly soiled or diluted.

NOTE: A clean potable water rinse following sanitization is not permitted under HFS 196, Appendix 7-204.11 of the Wisconsin Administrative Code (reference 40 CFR 180.940 (a)).

{Note to reviewer: The following graphic or a graphic of similar content may accompany any of the above food contact sanitization sections}



TO SANITIZE [SOFT SERVE] [FOOD] [AND] [FROZEN] [BEVERAGE] DISPENSING EQUIPMENT:

1. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
2. Fill equipment with a solution of (*insert appropriate dilution here*) [or equivalent dilution].
3. Allow solution to remain in equipment for at least 60 seconds.
4. Drain thoroughly [and allow to air dry] before reuse. Do not rinse.

TO SANITIZE ICE MACHINES:

1. Turn off refrigeration
2. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
3. Apply a solution of (*insert appropriate dilution here*) [or equivalent dilution] by mechanical spray, directly pouring, or by recirculating through the system.
4. Allow surfaces to remain wet or solution to remain in equipment for at least 60 seconds.
5. Drain thoroughly before reuse and allow to air dry.

TO SANITIZE SANITARY FILLING EQUIPMENT:

Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use-solution of (*insert appropriate dilution here*) [or equivalent dilution] for final washer and rinser applications. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly [and allow to air dry] before reuse. Do not rinse.

TO SANITIZE BEER FERMENTATION AND STORAGE TANKS:

Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use-solution of (*insert appropriate dilution here*) [or equivalent dilution] for mechanical or automated systems. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly [and allow to air dry] before reuse. Do not rinse.

WATERPROOF GLOVE SANITIZING DIRECTIONS

To prevent cross contamination into processing areas of food plants, waterproof gloves must be sanitized prior to entering or re-entering those areas. Remove visible contamination from gloves before sanitizing. Then place gloved hand in a use-solution of (*insert appropriate dilution from box above here*) for at least [sixty seconds] [one minute]. Change the solution in the bath at least daily or more often if the solution appears visibly diluted or soiled.

SANITIZING – NON-POROUS GLOVED HANDS:

To prevent the spreading of organisms into animal areas and the packaging and storage areas of food plants, dip, soak or spray pre-washed [plastic, latex or other synthetic rubber] gloved hands so that there is enough sanitizing solution to cover the gloved area. Do not let sanitizing solution come in contact with exposed skin. Make up the sanitizing solution by adding (*insert appropriate dilution from box above here*). Dip, soak or spray in solution and allow gloved hands to remain wet for at least 60 seconds. No potable water rinse is allowed. Change the sanitizing solution in the bath at least daily or when solution appears dirty.

TO SANITIZE EGG SHELLS INTENDED FOR FOOD:

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants, spray with a use-solution of (*insert appropriate dilution here*) [or equivalent dilution]. The solution must be equal to or warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Allow one minute contact time. Eggs sanitized with this product shall be subjected to a potable water rinse only if they are to be broken immediately for use in the manufacture of egg products. Eggs must be reasonably dry before casing or breaking. The solution must not be re-used for sanitizing eggs.

Note: Only clean, whole eggs can be sanitized. Dirty, cracked or punctured eggs cannot be sanitized.

FOR CONTINUOUS TREATMENT OF CONVEYORS:

Remove visible food particles and excess soil by a pre-flush or pre-scrape. Wash with a good detergent or compatible cleaner. Rinse equipment thoroughly with potable water, then rinse equipment with a sanitizing solution. During processing, apply **Carbosan 20D** at *(insert appropriate dilution from box above here)* to conveyors with MIKRO MASTER or other suitable feeding equipment. Controlled volumes of sanitizer are applied to return portion of conveyor through nozzles so located as to permit maximum drainage of sanitizer from equipment and to prevent puddles on top of belt. During interruptions in operation, coarse spray equipment, peelers, collators, slicers and saws with MIKRO MASTER dispensed **Carbosan 20D** solution of *(insert appropriate dilution from box above here)*. Conveyors and other equipment must be free of product when applying this coarse spray. Use *(insert appropriate dilution from box above here. Must be 200 ppm AI Minimum)* in Wisconsin dairy processing facilities.

{For food processing or other facilities that have installed entryway sanitizing systems:}

ENTRYWAY SANITIZING SYSTEMS: *{Not approved for Use in California}*

To prevent cross contamination from area to area, set the system to deliver [1/4 – 1/2 fl. oz. per gallon of water] [or equivalent dilution] [400 – 800 ppm active] of sanitizing solution. The [spray] [foam] must cover the entire path of the doorway. Set the system so that a continuous wet blanket of sanitizer solution is delivered to the floor.

Do not mix other foam additives to the sanitizing solution.

SHOE BATH SANITIZER DIRECTIONS:

To prevent cross contamination into animal areas [and the packaging and storage areas of food plants], shoe baths containing one inch of freshly made sanitizing solution must be placed at all entrances to buildings [and hatcheries]. Scrape waterproof work [boots] [shoes] and place in a use-solution of 1/8 fl. oz. of **Carbosan 20D** per gallon of water [or equivalent dilution] [200 ppm] for 60 seconds prior to entering area. [If there is a visible soil load or excessive traffic place work [boots] [shoes] in a use-solution of 1/4 – 1/2 fl. oz. per gallon of water [or equivalent dilution] [400 – 800 ppm active quat.]. Change the solution in the bath at least daily or more often if the solution appears diluted or soiled.

SHOE FOAM SANITIZER DIRECTIONS: *{Not approved for Use in California}*

To prevent cross contamination into animal areas, and the packaging and storage areas of food plants. Apply a foam layer approximately 1/2 to 2 inches thick made from a solution of 1/2 to 3/4 fl. oz. of **Carbosan 20D** per gallon of water [or equivalent dilution] [800 to 1200 ppm active], at all entrances to buildings, hatcheries, production and packaging rooms by using a foam generating machine or aerator to apply the foam layer. Follow the foaming directions as specified by the manufacturer of the foam generator or aerator. Scrape waterproof work [boots] [shoes]. Stand or walk through foamed area for 60 seconds prior to entering area. Foam area must be washed and foam replaced at least daily or more often if the foam appears visibly diluted or soiled.

TO DEODORIZE: [Mix] [Use] [1/2 oz.] or [1/2 - 1 fl. oz.] or [1/2 – 2 fl. oz.] of **Carbosan 20** per gallon of water to deodorize surfaces. Apply using a cloth, mop, sponge or sprayer. Wipe or allow to air dry.

Carbosan 20D is effective at eliminating odors on porous surfaces such as upholstery, drapes, carpets, bedding, shower curtains, mattresses and non-porous surfaces such as walls and floors. Excellent for fire restoration.

DEODORIZING DIRECTIONS:

Nursing Homes, Hotels, Schools, Restaurants: Using [1/2 - 1 fl. oz.] or [1/2 – 2 fl. oz.] in chemical toilets, waste receptacles, bed pans, drainage bottles, diaper pails, hampers, disposals, commodes and air conditioner pans will eliminate odors.

Mopping Solutions, Automatic Scrubbers: Use [1/2 - 1 fl. oz. per gallon] or [1/2 - 2 fl. oz.] per gallon of cleaning solution eliminates undesirable odors.

Laundry: [1/2 - 1 fl. oz.] or [1/2 - 2 fl. oz.] per load added during the final rinse cycle deodorizes all offensive odors.

Air Freshener/Automotive Uses: 2 fl. oz. per gallon of water or desired concentration will effectively neutralize damp musty odors caused by mildew in storage areas, basements, closets and bathrooms.

Carbosan 20D

EPA Reg. No. 6836-357

EPA Notification 2015-06-24 EPA Submission 2020-05-07

Effective on smoking and cooking odors (garlic, fish, onions, etc.). Automobile odors from tobacco, musty carpet smell and beverage smells will be eliminated.

Carpets: [$\frac{1}{2}$ - 1 fl. oz.] or [$\frac{1}{2}$ - 2 fl. oz.] per gallon of shampoo solution eliminates odors associated with urine, vomit, smoke, and mildew. Reapply after cleaning for freshening effects. Allow to dry.

RV Holding Tanks: Toilet waste: cover bottom of holding tank with water and add [$\frac{1}{2}$ - 1 fl. oz.] or [$\frac{1}{2}$ - 2 fl. oz.] If odors return before time to empty, simply add [$\frac{1}{2}$ - 1 fl. oz.] or [$\frac{1}{2}$ - 2 fl. oz.] to the tank. Kitchen waste: [$\frac{1}{2}$ - 1 fl. oz.] or [$\frac{1}{2}$ - 2 fl. oz.] of Carbosan 20D to gray water tank as needed to control malodors created by dirty dish water.

Pet Odors: Use 2 - 3 fl. oz. per gallon of water or desired concentration, for urine, feces, and vomit, in carpet and upholstery. Clean prior to application then spray onto affected areas. Test hidden area for colorfastness. Allow 10 minutes contact time. Then blot with clean cloth. Allow to dry. Also effective on pet bedding and litter boxes.

Sewage Backup, Water Damage: Use 1 – 2 fl. oz. per gallon of water or desired concentration. Spray over affected areas before and after cleaning and extraction. Allow ten minutes contact time. Use proper ventilation; open windows.

CLEANING SOLUTION: Dilute [$\frac{1}{2}$ - 1 fl. oz.] or [$\frac{1}{2}$ - 2 fl. oz.] per gallon of water for cleaning of kitchen counters, tables, walls, bathrooms, toilet seats, mopping floors and large routine applications.

¹ when used according to disinfection directions

² Allow surface temperature to reach room temperature before applying product.

{Note to reviewer: For Nonrefillable Containers, Label has Household and Residential Uses}

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

{or}

Store in original container in areas inaccessible to children. Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for reconditioning if appropriate.

{Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products. Chapter 13, Table 6 of the Label Review Manual states that for “All products in containers that could be burned,” the registrant has the option to “Remain silent on burning;” therefore, no incineration language is provided for plastic containers.}

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Open dumping is prohibited. Store in original container in areas inaccessible to children.

Pesticide Disposal:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

[Plastic and Metal Containers:] Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

[Metal containers only:] DO NOT cut or weld metal containers.

[Bag in Box Containers:] Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

{Note to reviewer: For Nonrefillable Sealed Containers: Several packaging options are designed for use dilution systems with sealed containers or bottles to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are closed sealed containers. The following text will be used on these sealed container types:}

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Open dumping is prohibited. Store in original container in areas inaccessible to children.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash [or offer for recycling]

PACKET LABEL TO BE USED WITH MASTER CONTAINER LABEL
FOR SANITIZATION

Note to reviewer: the following will be used for 3 fl. oz. of concentrate:
MIX EACH PACKET WITH 5 GALLONS OF WATER

{If other packet sizes are desired, new packet label will be identical and the only things that will vary are the net contents, amount of water to dilute with and ppm active quat. Those 3 items will have to match or be equivalent to the dilution chart that is shown on page 9.}

CARBOSAN 20D

Active Ingredients:	
Didecyl dimethyl ammonium carbonate and Didecyl dimethyl ammonium bicarbonate	20.0%
Other Ingredients.....	80.0%
Total.....	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

See outer container for Precautionary Statements and Use directions

Disposal: Nonrefillable container. Do not reuse packet. Wrap and put in trash.

[Not for retail sale]

EPA. Reg. No. 6836-357
EPA. Est. No. *(insert EPA Est. No. here)*
Net Contents: *(insert container size here)*

Lonza, LLC
412 Mount Kemble Avenue, Suite 200S
Morristown, NJ 07960

{Note to reviewer: The following is considered optional graphics and marketing language.}

{For Bag-in-Box Containers:}

For Bag – In – Box Containers:

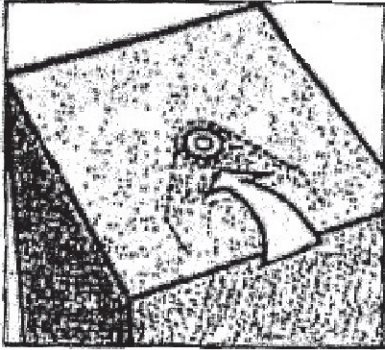
How to use this package:

This package is designed to be used with dilution control systems only. Open package and connect to dispenser according to directions on box top.

Trigger Sprayers:

Fill bottle from dispenser.

Apply to surfaces as specified in directions above.

OPENING INSTRUCTIONS <ol style="list-style-type: none">1. Position box with perforation up.2. Press in circle.3. Lift flap/tear along perforation.4. Retrieve fitting on bag.5. Remove clear dust-cap from bag fitting.6. Twist dispenser connector onto bag fitting.7. Place bag-in-box into position on dispenser shelf.8. Close dispenser (if applicable).		INSTRUCCIONES PARA ABRIR <ol style="list-style-type: none">1. Ponga la caja con la perforación hacia arriba.2. Empuje el círculo hacia adentro.3. Levante la persona arrancándola de la caja a lo largo de la perforación.4. Saque el adaptador que está en la bolsa.5. Quite la tapa transparente contra el polvo que tiene el adaptador de la bolsa.6. Enrosque el conector del dispensador al adaptador.7. Ponga la "bag-in-box" (bolsa en caja) en posición en el mostrador de despacho.8. Cierre el dispensador (si corresponde).
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